

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

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Remarks

Claim 15 is here amended. Support for this amendment is found in claim 15 as originally filed.

Claims 1-21 are pending in the application. No new matter has been added, and no new material presented that would necessitate an additional search on the part of the Examiner.

Claims are not obvious

The Office Action on page 2, ¶3 rejects claims 1-21 under 35 U.S.C. §103(a) in view of Tanaka (U.S. Patent Number 5,827,175, issued October 27, 1998) in combination with Rabiner et al. (U.S. Patent Number 6,524,251, issued February 25, 2003).

Prior to analyzing the art cited in the Office Action, Applicants believe that a brief description of the subject matter of independent claims 1, 9, 15 and 21 would be of use to the Examiner.

Claim 1 is directed to an endoscopic imaging apparatus with an endoscope including a distal end, at least one ultrasound transducer within the distal end, and a covering fabricated from an electrically insulating material with a Thermal Conductance greater than 1 W/M-°K overlaying at least a portion of the distal end.

Claim 9 is directed to an apparatus for dissipating thermal energy produced by an endoscopic imaging apparatus. The apparatus is configured and dimensioned to mate with a distal end of the imaging apparatus for dissipating thermal energy produced at the distal end, and is fabricated from an electrically insulating material with a Thermal Conductance greater than 1 W/M-°K.

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

Date of Deposit: May 5, 2006

Claim 15 as here amended is directed to a method for scanning a patient's heart using a TEE probe with steps of providing an endoscope with a distal end with a portion fabricated from an electrically insulating material with a Thermal Conductance greater than 1 W/M-°K, and guiding the endoscope including a distal end to obtain a scan of the patient's heart.

Claim 21 is directed to a device for passively dissipating thermal energy produced by at least one transducer located at a distal end of an endoscopic imaging apparatus. The device is configured and dimensioned to encase the transducer, and has the following properties: electrically insulating; a Thermal Conductance greater than 1 W/M-°K; and substantially non-reactivity in the presence of bodily fluids.

Applicant's claims describe an apparatus, a Transesophageal Echocardiogram (TEE) probe, for scanning organs, for example, the heart. A heart is an essential organ that never or rarely is ablated for a medical purpose. Prior art devices are susceptible to overheating and can cause esophageal burns, and can be used for only a short period of time. See specification as published, paragraph [0004]. Applicant's claims are directed to electrically insulated probes.

Tanaka, U.S. Patent Number 5,827,175, issued October 27, 1998

Tanaka shows an endoscopically inserted ultrasound probe with a large ultrasound transducer. See Tanaka, column 2, lines 23-26. The transducer is larger than the inside diameter of the biopsy or instrument channels on the part of the endoscope. Ibid., column 2, lines 26-27. Tanaka's probe transmits low-frequency and high-power ultrasound pulse signals from an ultrasound transducer on a probe head. Ibid., column 2, lines 28-31.

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

Date of Deposit: May 3, 2006

Tanaka fails to teach or suggest a covering for an ultrasound transducer within an endoscope that is fabricated from an electrically insulating material, as is the subject matter of Applicant's claim 1. Tanaka also fails to teach or suggest an electrically insulating material with a Thermal Conductance greater than 1 W/M-°K, as is the subject matter of Applicant's claims 1, 9, 15 and 21. Tanaka fails even to mention any insulating or thermal conductance properties of a material for covering a transducer.

Tanaka is silent as to the material makeup of the end cap, as admitted by the Office Action on page 2. Further, Tanaka fails to teach or suggest a device for dissipating thermal energy produced by a transducer, as is the subject matter of Applicant's claims 9 and 21.

For any of these reasons, Tanaka alone does not render any of the present independent claims, and other claims that depend directly or indirectly from them, obvious. Rabiner et al., U.S. Patent Number 6,524,251, issued February 25, 2003

Rabiner et al., cited in combination with Tanaka, shows a shielded ultrasonic probe operating in transverse mode for ablating and removing undesired tissue. See Rabiner et al., column 1, lines 12-14. Rabiner et al. shows a means for controlling, directing and focusing the cavitation energy from the probe by utilizing a sheath extending circumferentially along the longitudinal axis of the probe. Ibid., column 4, lines 3-7.

Rabiner et al. clearly explains that the purpose of cavitation is to destroy tissue:

Typically, the energy produced by an ultrasonic probe is in the form of very intense, high frequency sound vibrations, results in fragmentation of tissue (plaque and thrombosis) either as a result of mechanical action thereon or "cavitation" thereof, in which high energy ultrasound frequency applied to liquids generates vapor-filled microbubbles or "cavities" with the concomitant rapid expansion and collapse of the cavities that is accompanied by intense localized hydraulic shock, that causes fragmentation or dissolution of tissue. Medical applications for ultrasonic probes providing cavitation include surgical procedures for the ablation of tissues.

10/764,951
Response to Office Action of March 6, 2006
Via facsimile 571-273-8300
Date of Deposit: May 5, 2006

Attorney Docket Number US 030082

for example, treatment of cancer, tissue remodeling, liposuction, and removal of vascular occlusions. [See Rabiner et al., column 1, lines 28-41, emphases added]

Unlike Applicant's claims, which address scanning organs and tissues using electrically insulated probes in order to minimize damage, Rabiner's probes destroy tissues.

Accordingly, Rabiner et al. fails to teach an apparatus for dissipating thermal energy produced by an endoscopic imaging apparatus, as is the subject matter of Applicant's claims 9 and 21. Rabiner et al. also fails to teach or suggest a device for passively dissipating thermal energy produced by a transducer, as is the subject matter of Applicant's claim 21. Further, Rabiner et al. fails to teach or suggest a covering overlaying the distal end of an endoscope that is fabricated from an electrically insulating material having a Thermal Conductance greater than 1 W/M-°K, as is the subject matter of Applicant's claim 1.

Most important, Rabiner et al. teaches away from the present claims, because, first, Rabiner's probe is used to ablate and remove undesired tissue. Second, Rabiner et al. fails to teach or suggest any method for scanning a patient's heart, let alone scanning using a TEE probe, as is the subject matter of Applicant's claim 15 as here amended. Third, Rabiner et al. also teaches away from the present claims by showing the use of irrigation fluids as a means of cooling the probe. See Rabiner et al., column 9, lines 43-44. Rather, Applicant's claim 21 is directed to passively dissipating thermal energy produced by a transducer.

As Rabiner et al. fails to cure the defects of Tanaka with respect to claims 1, 15, 19 and 21, and as Rabiner et al. teaches away from the subject matter of the present claims, therefore claims 1, 15, 19 and 21 are not obvious in view of Tanaka and Rabiner et al., alone or in combination.

10/764,951
Response to Office Action of March 6, 2006
Via facsimile 571-273-8300
Date of Deposit: May 5, 2006

Attorney Docket Number US 030082

Claims 2-14, 16-18 and 20 depend directly or indirectly from claims 1, 15, and 19 and therefore incorporate all of the subject matter of these claims. As Rabiner et al. fails to cure the defects of Tanaka with respect to claims 1, 15, 19 and 21, therefore claims 1-21 are not obvious in view of Tanaka and Rabiner et al., alone or in combination.

Applicants respectfully request that this rejection be withdrawn.

Legal analysis

Whether an invention would have been obvious under 35 U.S.C. §103(a) is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

The *Manual of Patent Examining Procedure* states: "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." [emphases added] *Manual of Patent Examining Procedure* §2142 (8th Ed. Rev.2, May 2, 2004); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully traverse the rejection, and show that the facts of the case and the relevant case law indicate that the invention would not have been obvious to one of ordinary skill in the art, at the time the application was filed, for the following reasons.

10/764,951
Response to Office Action of March 6, 2006
Via facsimile 571-273-8300
Date of Deposit: May 5, 2006

Attorney Docket Number US 030082

To establish a *prima facie* case for obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *Manual of Patent Examining Procedure*, §2143.03, p. 108 (8th Ed. Rev.2, May 2, 2004); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). We show above that none of the references alone or in any combination teach or suggest all of the claim limitations.

Analysis of references combined

To establish obviousness based on a combination of the elements disclosed in the prior art in the absence of any hindsight, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *Id.* The teaching or suggestion, not merely to make the claimed combination, but also of a reasonable expectation of success, must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488; 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Rabiner et al., the most recently published of the cited references, fails to cite to or refer to Tanaka. Under the legal criteria discussed above, Rabiner et al. fails to provide any motivation for making any combination with Tanaka, let alone that such a combination would be successful. As there is no citation in Rabiner et al. to Tanaka, there can be no teaching or suggestion to combine Rabiner et al. with Tanaka. For these reasons also, the combination of these references fails to teach or suggest the present claims.

As neither Tanaka nor Rabiner et al. provides any explicit nor implicit motivation to one of ordinary skill in the art to have combined any elements of these primary references to have arrived at the present claims of Applicant's invention, then making the combination is

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

Date of Deposit: May 5, 2006

using Applicant's own specification as a blueprint to reconstruct the invention, which is impermissible hindsight, viz., extracting merely an element or word from each reference, to attempt to reconstruct Applicant's claims when neither reference explicitly or implicitly teaches or suggests such a combination, let alone teaches or suggests a reasonable expectation of success.

The knowledge generally available to one of ordinary skill in the art would not have rendered the claims of the present invention obvious

The Office Action is correct that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, found either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art. However, the legal criteria to determine the extent to which such knowledge is in the general art, rather than in a specification, has been extensively addressed by recent court decisions analyzed below.

In *Ruiz v. A.B. Chance Company*, 357 F.3d 1270; 69 U.S.P.Q.2d 1686 (Fed. Cir. 2004), the court found that the two cited prior art references both addressed precisely the same problem: the use of screw anchors to underpin existing structural foundations. The court explained that motivation to combine two references was found in the nature of the problem to be solved because the two cited references in this case addressed precisely the same problem of underpinning existing structural foundations. *Id.* at 1276. The court further stated that because the prior art references address the narrow mechanical problem of underpinning existing building foundations, a person seeking to solve that exact same problem would have consulted the references and applied their teachings together. *Id.* *Ruiz* thus provides only a very narrow scenario for when the nature of the problem can provide

10/764,951
Response to Office Action of March 6, 2006
Via facsimile 571-273-8300
Date of Deposit: May 5, 2006

Attorney Docket Number US 030082

implicit motivation to combine references, requiring the prior art references cited to address precisely the same problem as the current invention.

A second recent case, *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*, 357 F.3d 1319, 69 U.S.P.Q.2d 1641 (Fed. Cir. 2004), similarly addresses the issue of when motivation to combine references can be considered proper. In *National Steel Car*, the claims at issue were directed to a railcar with a "drop deck". *Id.* at 1322. In *National Steel Car*, the court determined that the motivation to combine the two prior art references is implicit in the knowledge of one of ordinary skill in the art, because both of the two references independently arrived at the "drop deck" railcar design. See *Id.* at 1337-1340. Since two different inventors in the field independently arrived at the claimed invention, the court decided that the motivation to combine the two cited prior art references was implicit in the knowledge of one of ordinary skill in the art. See *Id.*

In the present case, Tanaka addresses an endoscopically inserting ultrasound probe with a large ultrasound transducer, where the transducer is larger than the inside diameter of the biopsy or instrument channels on the part of the endoscope. See Tanaka, column 2, lines 23-27.

Rabiner et al. addresses a shielded ultrasonic probe for ablating and removing undesired tissue. See Rabiner et al., column 1, lines 12-14. Rabiner et al. also shows a means for controlling, directing and focusing the cavitation energy from the probe by utilizing a sheath that extends circumferentially along the longitudinal axis of the probe. *Ibid.*, column 4, lines 3-7.

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

Date of Deposit: May 5, 2006

These references neither teach nor suggest how to modify any of the technology of the other reference in order to combine with the other reference to arrive at the subject matter of the claims of the present application. Therefore, clearly, the narrow holdings of *Ruiz* and *National Steel Car* are inapposite to the present claims.

The facts of *Ruiz* and *National Steel Car* are readily distinguishable from the facts of the present case. In contrast to *Ruiz*, neither of the prior art references addresses precisely the same problem as each other, or as the present claims. Unlike in *National Steel Car*, in the present case there is no prior art disclosure that teaches or suggests all of the elements of Applicant's claims. Additionally, there is no prior art reference that discloses the combination of references cited by the Office Action. The lack of teachings by others of the Applicant's claims distinguishes the present case from both *Ruiz* and *National Steel Car*, and demonstrates that the motivation to combine the references cited by the Office Action was not implicit in the knowledge generally available to one of ordinary skill in the art at the time the present application was filed.

Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there can be no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). The substantial changes to the technologies that would have been required to be made in each of Tanaka and Rabiner et al. in making the combination, would have rendered each technology in Tanaka and in Rabiner et al. unsuitable for each asserted use. Tanaka's device is inserted in a body cavity to scan body tissues. Rabiner's device is used to destroy tissue. The combination of Tanaka and Rabiner et al. cannot be made.

10/764,951

Attorney Docket Number US 030082

Response to Office Action of March 6, 2006

Via facsimile 571-273-8300

Date of Deposit: May 5, 2006

From this analysis it is clear that the present claims have been used as a blueprint to pick and choose references to reconstruct the invention, which is impermissible hindsight.

For any of these reasons, Applicants assert that the present claims comply with 35 U.S.C. §103(a), and respectfully request that rejection of claims 1-21 under 35 U.S.C. §103(a) be withdrawn.

Summary

On the basis of the foregoing reasons, Applicants respectfully submit that the pending claims are in condition for allowance, which is respectfully requested.

If there are any questions regarding these remarks, the Examiners are invited and encouraged to contact Applicant's representative at the telephone number provided.

Respectfully submitted,



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